Full Text AR-93-02

SPECIALIZED CENTER OF RESEARCH IN SYSTEMIC LUPUS ERYTHEMATOSUS

NIH GUIDE, Volume 21, Number 43, November 27, 1992

RFA: AR-93-02

P.T. 04

Keywords:
Autoimmunity
Biomedical Research, Multidiscipl
Disease Prevention+
Treatment, Medical+

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Letter of Intent Receipt Date: March 1, 1993
Application Receipt Date: April 20, 1993

PURPOSE

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invites applications for Specialized Centers of Research (SCORs) in systemic lupus erythematosus. A SCOR is envisioned as a national resource associated with a major medical complex and dedicated to furthering the research effort related to systemic lupus erythematosus. A SCOR should foster a concerted research effort that strongly emphasizes basic disciplines, but also involves significant interaction between basic research and clinical investigations of systemic lupus erythematosus.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), Specialized Center of Research in Systemic Lupus

Erythematosus, is related to the priority area of chronic disabling conditions. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government that have established clinical programs in rheumatology and research in systemic lupus erythematosus. Foreign organization are ineligible. International collaborations in domestic applications will only be accepted if the resources are clearly shown to be unavailable in the United States.
Applications from minority individuals and women are encouraged.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) specialized center grant (P50). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. The total project period for applications submitted in response to the present RFA should be five years. The anticipated award date is September 30, 1993. The direct costs requested cannot exceed $500,000 each year. Future SCOR awards or renewals will be by RFA only.

FUNDS AVAILABLE

The estimated funds (total costs) available for the first year of support for new SCORs is $1.5 million. Two awards are anticipated. However, funding will be contingent on receiving applications judged by peer review to be highly meritorious.

RESEARCH OBJECTIVES

A SCOR consists of at least three individual, but interrelated, basic and clinical research projects, each with high scientific merit and clear research objectives and, in the aggregate, devoted to a specific major health area. Ongoing projects may be absorbed into the SCOR if their original funding source is relinquished. Funding may also be requested for one or more core resources.

A core is defined as a resource shared by several investigators that should enhance research productivity and increase the functional capacity of the SCOR.

The objective of this SCOR program is to expedite development and applications of new knowledge of specific importance to systemic lupus erythematosus, to learn more about the etiology of this disease, and to foster improved approaches to treatment and/or preventions. A SCOR should provide a multidisciplinary approach and utilize both laboratory and clinical research to focus on systemic lupus erythematosus. The proposed SCOR should provide for a mutually supportive interaction between basic scientists and clinical investigators. Research programs may vary at each institution according to local expertise, interests, and resources. Emphasis in the proposed projects should be on the elaboration of new and significant hypotheses, development of innovative approaches, and generation of improved strategies for approaching current issues relating to systemic lupus erythematosus.

Specific research issues were identified in the workshop, "Future Research Agenda: Systemic Lupus Erythematosus," sponsored by the NIAMS and held January 13 and 14, 1992, in Bethesda, Maryland. These topics, although not necessarily all of them, are expected to be targeted in a successful SCOR. Special emphasis should be placed on systemic lupus erythematosus as a disease more common in women, and especially in black women.

Potential areas of inquiry include, but are not limited to:

o mechanisms of immunologic tolerance;

o immunoregulatory defects characteristic of systemic lupus erythematosus;

o mechanisms of tissue injury;

o induction and perpetuation of autoantibody functional effects of autoantibody on cell biology;

o genetic controls of disease onset and persistence;

o consequences of gender (why are females predominantly affected), including the effects of oral contraceptives and estrogen replacement therapy;

o biologic differences among ethnic groups, including cross-cultural studies and studies of migrants;

o treatment: novel treatment trial strategies; measurement criteria; strategies to diminish toxicity; strategies to accelerate the development of new agents; and treatment during pregnancy.

A copy of the notes from this workshop will be included in the guidelines obtained from the contact person listed below.

Institutions With General Clinical Research Centers

Applicants from institutions that have a General Clinical Research Center (GCRC) funded by the NIH National Center for Research Resources may wish to identify the GCRC as a resource for conducting the proposed research. Details of the interactions of the SCOR staff with the GCRC staff and research personnel may be provided in a statement describing the collaborative linkages being developed. A letter of agreement from the GCRC Program Director must be included with the application.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH policy is that applicants for NIH clinical research grants and cooperative agreements are required to include minorities and women in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder or condition under study; special emphasis must be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or inadequately represented in clinical research, particularly in proposed population-based studies, a clear compelling rationale must be provided.

The composition of the proposed study population must be described in terms of gender and racial/ethnic group. In addition, gender and racial/ethnic issues must be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included in the form PHS 398 (rev. 9/91) in Sections 1-4 of the Research Plan AND summarized in Section 5, Human Subjects. Applicants are urged to assess carefully the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include

representation of the full array of United States racial/ethnic minority populations (i.e., Native Americans [including American Indians or Alaskan Natives], Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research is defined as human biomedical and behavioral studies of etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including, but not limited to, clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities when it is important to apply the results of the study broadly, and this should be addressed by applicants.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will address specifically whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and reflected in assigning the priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants or cooperative agreements that do not comply with these policies.

LETTER OF INTENT

Prospective applicants are asked to submit, by March 1, 1993, a letter of intent that includes a descriptive title of the proposed research projects, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted.

Although a letter of intent is not required, is not binding, and does not enter into the review of subsequent applications, the information that it contains allows NIAMS staff to estimate the potential review workload and to avoid conflict of interest in the review.

The letter of intent is to be sent to:

Dr. Julia B. Freeman
Centers Program, Extramural Programs
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 403
Bethesda, MD 20892
Telephone: (301) 402-3348
FAX: (301) 480-7881

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for these grants. These forms are available at most institutional offices of sponsored research and from the Office of Grants Inquiries, Division of Research Grants, National Institutes of Health, 5333 Westbard Avenue, Room 449, Bethesda, MD 20892, telephone 301/496-7441.

Special guidelines have been developed for the SCOR program in the NIAMS. These guidelines must be used in assembling the application. The guidelines may be obtained by contacting the Centers Program Director listed above.

The RFA label available in the PHS 398 (rev. 9/91) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2a of the face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240

Bethesda, MD 20892**

At the time of submission, two additional copies of the application must also be sent to:

Dr. Tommy L. Broadwater
Chief, Review Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 405
Bethesda, MD 20892

Applications must be received by April 20, 1993. If an application is received after that date, it will be returned to the applicant without review. The Division of Research Grants (DRG) will not accept any application in response to this announcement that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by the DRG and responsiveness by the NIAMS. Incomplete applications will be returned to the applicant without further consideration.

Applications may be triaged by an NIAMS peer review group on the basis of relative competitiveness. The NIH will withdraw from further competition those applications judged to be non-competitive for award and notify the applicant Principal Investigator and institutional official. Those applications judged to be competitive will undergo further scientific merit review. Those applications that are complete and responsive will be evaluated in accordance with the criteria stated below for scientific/technical merit by an appropriate peer review group convened by NIAMS. The second level of review will be provided by the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

Review criteria for this RFA are generally the same as those for unsolicited research grant applications:

o scientific, technical, or medical significance and originality of proposed research;

o appropriateness and adequacy of the experimental approach and methodology proposed to carry out the research;

o qualifications and research experience of the Principal Investigator and staff, particularly, but not exclusively, in the area of the proposed research;

o availability of the resources necessary to perform the research;

o appropriateness of the proposed budget and duration in relation to the proposed research;

Additional scientific/technical merit criteria specific to the objectives of the SCOR program include:

o scientific merit of combining the component parts into a SCOR;

o technical merit and justification of each core unit;

o adequacy of plans for interaction among investigators, and the integration of the various projects and core units;

o qualifications, experience and commitment of the SCOR Director and his/her ability to devote time and effort to provide effective leadership;

o scientific and administrative structure, including internal and external procedures for monitoring and evaluating the proposed research and for providing ongoing quality control and scientific review.

Each project will be assigned a separate priority score, taking into consideration only its merit as an individual research project.

AWARD CRITERIA

The anticipated date of award is September 30, 1993.

The primary factors determining the award will be the priority score and the availability of funds. Since the NIAMS is interested in funding only the best research, individual research projects of lesser quality may not be funded, even if approved, under the "umbrella" of the SCOR

mechanism. In addition, it is obviously important that each project fit in with, and contribute to, the theme of the overall SCOR.

INQUIRIES

Written and telephone inquiries concerning this RFA are encouraged.
The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Dr. Julia B. Freeman
Centers Program, Extramural Programs
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 403
Bethesda, MD 20892
Telephone: (301) 402-3348
FAX: (301) 480-7881

Direct inquiries regarding fiscal matters to:

Mara H. DeKemper
Grants Management Officer
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 732
Bethesda, MD 20892
Telephone: (301) 496-0552

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research. Awards will be made under the authority of the Public Health Service Act, Title III, Section 301 (Public Law 410, 78th Congress, as amended, 42 USC 241) and administered under PHS grants policies and Federal regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

Return to RFAs Index
Return to NIH Guide Main Index